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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,073	04/09/2001	Ke-Wen Dong	#651	7413

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EXAMINER
COOK, LISA V

ART UNIT	PAPER NUMBER
1641	8

DATE MAILED: 11/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/829,073	DONG ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *10-18,20 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 19* is/are rejected.

7)☒ Claim(s) *1* is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

1. Applicant's election of Group I (claims 1-9 and 19), with traverse for prosecution in the subject application is acknowledged. Because Applicant did not distinctly and specifically points out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

In response to the Non-sequence compliance mailed 22 May 2002, Applicant's Raw sequence listing (filed 7/10/02) has been entered.

2. Currently, Claims 1-9, and 19 are under consideration.

Drawings

3. The drawings in this application are objected to by the Draftsperson under 37 CFR 1.84 or 1.152 (see PTO-948).

Information Disclosure Statement

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on form 1449 has cited the references they have not been considered.

5. The information Disclosure Statement filed 8/5/02 has been considered as to the merits before first action.

Specification

6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

I. Page one of the disclosure is not numbered.

II. Sequence identification numbers are listed in the drawing and the specification. (For example see page 8 and Figure 2). The corresponding seq. id no. 1-7 should be added at each sequence recitation.

III. The abstract of the disclosure is objected to because it is not clear if line 18 should read "complex form" or "complex formed". Clarification is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-9 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 1 is objected to because of the following informalities: The claim refers to the "complex form" instead of the "complex formed". It is not clear if this is a typo. "Complex form" does not clearly identify the complex formed a prior in the claim. As recited it reads on any complex form, which may have been produced by some other means. Appropriate correction required.

B. Claim 1 is vague and indefinite. The method merely measure the formation of a complex between human zona pellucid protein 3 and sperm, but the claim does not correlate this formation to sperm activity.

C. Claim 1 and 19 are vague and indefinite in utilizing the terms "appropriate concentration", "appropriate amount" and "under conditions permitting" because they are not defined in the clams or the specification.

D. Claim 19 is vague and indefinite because it is unclear as to what "reagents will be employed in (b). The claim is directed to "reagents used for establishing the conditions for allowing the binding of sperm". As recited the metes and bounds of the claim cannot be determined. One of ordinary skill in the art would not be apprised of the scope of the invention. It is suggested that the actual reagents be included in the claim for clarity.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Duin et al. (Biology of Reproduction, 51, 607-617, 1994).

Van Duin et al. disclosed the expression and purification of human zona pellucida protein ZP3 produced by Chinese hamster ovary. The recombinant human zona pellucida protein ZP3 induces the human sperm acrosome reaction and promotes sperm egg fusion. See abstract and page 608, 1st column, 2nd paragraph.

ZP3 is a zona pellucida protein 3 as supported by the disclosure on page 2 lines 5-6. The protein concentration of ZP3 was measured in an immunoassay employing coated plates/matrix. The binding of ZP3 to sperm was also taught and evaluated via the human sperm acrosome reaction assay on page 61 and the hamster egg penetration assay on page 611. With respect to the protein concentration of ZP3, the reference outlined several different optimal concentrations of ZP3. In the ZP3 quantitative determination on page 610 the human zona pellucida contained approximately 5ng ZP3. In the human sperm acrosome reaction assay the concentration of recZP3 was 15-20ng/μl or .015-.020ng/ml. In the hamster egg penetration assay the final concentration of recZP3 raged from 2 to 32ng/ml. Therein reading on the different concentrations recited in claims 2-8.

II. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Van Duin (WO 92/03548).

Van Duin disclosed a polypeptide and functional derivatives thereof which have human ZP3 activity or human ZP3 antigenicity. The polypeptides can be produced either synthetically or by recombinant DNA technology. Specifically, the polypeptide to be expressed is coded for by a DNA sequence or more accurately a nucleic acid sequence. The nucleic acid sequence is optionally transcribed and translated to the target polypeptide via cloning into a vector transformed into a host cell. The vector may be self-replicating or it may integrate into the DNA of the host. (See page 2) Different host cells can lead to different polypeptides. (Prokaryotes are not adapted for glycosylation, Eukaryotes have the means of glycosylation, but yeast cells give a different glycosylation pattern than mammalian cells).

ZP3 binding to eggs and sperm are evaluated on page 11 and figure 7.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 2-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Duin (WO 92/03548).

Please see previous discussions of Van Duin as set forth above.

Van Duin differ from the instant invention in not specifically identifying the concentration of human zona pellucida protein ZP3.

However, Van Duin discloses the claimed invention except for specific concentrations of ZP3. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the concentration of reagents to the specific concentrations in claims 2-8 in a binding assay as a means of optimizing the assay, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

II. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Duin (WO 92/03548) in view of Maggio (Immunoenzyme technique I, CRC press © 1980, pages 186-187).

Please see Van Duin as set forth above.

Van Duin differs from the instant invention in not specifically teaching the detection assay in which one of the reagents is fixed to a matrix (i.e. micro titer plates).

However, Maggio disclose enzyme immunoassays wherein either the antigen or antibody is immobilized onto a solid phase. The solid phase can be particles, cellulose, polyacrylamide, agarose, discs, tubes, beads, or micro plates (micro titer plates). See page 186.

Van Duin and Maggio are analogous art because they are from the same field of endeavor, both inventions teach binding assay methods.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a matrix/micro titer plates as taught by Maggio in the assay method to detection ZP3/sperm binding of Van Duin because Maggio taught that micro plates or micro titer plates "are very convenient to wash thereby reducing labor in assay procedures". Page 186, last line.

III. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Duin et al. (Biology of Reproduction, 51, 607-617, 1994) or Van Duin (WO 92/03548) in view of Foster et al. (U.S.Patent#4,444,879).

The teachings of Van Duin et al. (Biology of Reproduction, 51, 607-617, 1994) or Van Duin (WO 92/03548) are set forth above. However, these references fail to teach the assay as a kit.

However, kits are well known embodiments for assay reagents. Foster et al. (U.S. Patent #4,444,879) describe one example. In their patent kits including the reactant reagents, a micro plate, positive controls, negative controls, standards, and instructions are taught. See figure 6, and column 15, lines 10-34.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the binding/detection assay as taught by Van Duin et al. (Biology of Reproduction, 51, 607-617, 1994) or Van Duin (WO 92/03548) and format them into a kit because Foster et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit. Further, the reagents in a kit are available in pre-measured amounts, which eliminates the variability that can occur when performing the assay.

11. For reasons aforementioned, no claims are allowed.

Remarks

12. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. by Harris (U.S.Patent#5,837,497) teach methods related to the purification and isolation of DNA sequences encoding the zona pellucida proteins from various mammalian species. The zona pellucida is a complex matrix surrounding the mammalian oocyte, formed of glycoproteins secreted by ovarian cells. Zone pellucida (ZP) glycoproteins perform a number of different functions. For example, the mouse ZP has been shown to provide structural integrity to the matrix, to be a sperm receptor in the matrix, to induce the sperm acrosome reaction on the surface of ZP, and to maintain binding between the sperm/egg as a secondary receptor. (Column 1, Lines 24-52)

In example 11, Harris et al. isolate and purify a human DNA sequences encoding human zona pellucida proteins ZPA and ZPB. These glycoprotein structures were found to be 92.6% homologous to the instant inventive products. (MPSRCH comparing protein-protein database search utilizing Smith-Waterman algorithm - A).

B. Ozgur et al. (Molecular Human Reproduction, Vol.4, No.4, pp.318-324, 1998) teach direct evidence of the binding process dependency upon the recognition of oligosacchardes sequences associated with zona pellucida glycoproteins.

C. Harris et al. (WO 94/11019) teach methods related to the purification and isolation of DNA sequences encoding the zona pellucida proteins from various mammalian species. The zona pellucida is a complex matrix surrounding the mammalian oocyte, formed of glycoproteins secreted by ovarian cells. Zone pellucida (ZP) glycoproteins perform a number of different functions. For example, the mouse ZP has been shown to provide structural integrity to the matrix, to be a sperm receptor in the matrix, to induce the sperm acrosome reaction on the surface of ZP, and to maintain binding between the sperm/egg as a secondary receptor. (Page 1 and Page 2) In example 11, Harris et al. isolate and purify a human DNA sequences encoding human zona pellucida proteins ZPA and ZPB. These glycoprotein structures were found to be 92.6% homologous to the instant inventive products. (MPSRCH comparing protein-protein database search utilizing Smith-Waterman algorithm - A).

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Lisa V. Cook
CM1-7B17
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11/3/02

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641